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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/057,596
Filing Date: January 24, 2002
Appellant(s): SHEPARD, DOUGLAS C.

Keum J. Park
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4-11-2006 appealing from the Office action mailed 4-15-05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Upon consideration, the reference of Forster et al (Am. J. Surg, vol. 156, No. 2, August 1988) is withdrawn from the rejections.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,855,234	HENDRICKSON	8-1989
5,788,678	ANTWERP	8-1998
6,569,688	SIVAN	5-2003
5,741,331	PINCHUK	4-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. Claims 1, 13-16, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendrickson (4,855,234) or Antwerp (5,788,678) by themselves or in combination further in view of Pinchuk (5,741,331).

Hendrickson discloses devices wherein enzymes catalase and papain are immobilized on the surfaces. This layer is further coated with a polymer (note columns, 4, 7-9 and claims 1 and 9).

Antwerp discloses indwelling catheters coated with fibrinolytic enzymes. The enzymes in turn are encapsulated and bonded to the surface of the catheter (columns 2-6 and claims).

These references however, do not teach the use of claimed block copolymer comprising polybutylene and acrylates or vinyl aromatics.

Pinchuk while disclosing implantable medical devices teaches that polymeric material made from block copolymers of polyolefin and styrene or acrylate is biostable and crack-resistant when implanted in vivo (abstract, col. 1, line 6 through col. 2, line 41, examples and claims).

The use of polymeric material made from block copolymers of polyolefin and styrene or acrylate in the medical devices if Hendrickson or Antwerp would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Pinchuk teaches that these block copolymers are biostable and crack-resistant when implanted in vivo.

Appellant's arguments have been fully considered, but are not found to be persuasive. Appellant argues none of these references discloses an enzyme (on an article) disposed within a polymer matrix, as required by the claims, or the specific block copolymers claimed. Appellant argues that the examiner has failed to recognize the structural significance of appellant's claimed polymeric matrix article wherein an enzyme is an integral part of the polymeric matrix and not merely coated or immobilized onto a solid surface. The examiner disagrees since each of the primary references teaches an article and a matrix in which the enzyme is immobilized. For example, Hendrickson clearly teaches devices (articles) and the enzyme is immobilized with the use of a polymer. Instant claim 1 recites, "the medical article having a matrix disclosed on said article". The examiner respectfully points out to the board that instant specification does not provide any specific definition of the term, 'matrix' and since in Hendrickson, the enzyme is surrounded by the polymer, it meets the requirements of the term, matrix.

Similarly, in Antwerp, the catheters are coated with encapsulated enzymes; the encapsulating material is a polymer. It is interesting to note that according to instant claims 14-20 the enzyme is attached to the surface; if so, it is unclear to the examiner as to how one can form a matrix around the enzyme since the side of the enzyme, which is attached to the article, will not have the polymer matrix. Therefore, appellant's assertion that coating such an immobilized enzyme with a polymer as taught by Hendrickson, would result in an enzyme being disposed under a matrix, rather than within a matrix as claimed and fail to have the claimed structure and/or function is not persuasive. For the same reason, appellant's arguments that Van Antwerp discloses an enzyme bound to the surface of a catheter that is then coated with a polysilicone or starch based "encapsulating coating and that there is disclosure of incorporation of the enzyme within a matrix or any block copolymers of any type are not persuasive. The examiner agrees with appellant that the primary references do not teach instantly claimed polymers which are used for immobilizing the enzymes. Hence the reason for combining the primary references with Pinchuk which teaches that polymeric material made from block copolymers of polyolefin and styrene or acrylate is biostable and crack-resistant when implanted in vivo. The examiner disagrees with appellant's argument that the examiner fails to appreciate the purpose articulated in claim 1 which the cited reference do not teach or even suggest: that is, creating enzyme activity in the matrix while at the same time, allowing diffusion of substrates into and diffusion of products out of the matrix. The examiner points out that appellant has not shown that the prior art articles do not perform this function. Appellant argues that Pinchuk

discloses block and star copolymers for various types of implantable medical devices, but there is no teaching in Pinchuk of an enzymatically active polymeric matrix, nor does it appear to be any teaching regarding diffusion of enzymatic substrates into, and diffusion of enzymatic precuts out of, a matrix. These arguments are not found to be persuasive since as pointed out above, appellant has not shown that the prior art articles do not perform this function and the reference is combined for Pinchuk's teachings of biostability of the polymers when implanted. The rationale for the use of the polymers of Pinchuk need not be the same as appellant's.

2. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendrickson or Antwerp or Forster by themselves or in combination in further combination with Pinchuk (5,741,331) as set forth above, further in view of applicant's statements of prior art.

The teachings of Hendrickson, Antwerp, Forster and Pinchuk have been discussed above. What is lacking in these references is the teaching of immobilizing the enzymes on the medical article through antibody antigen interactions or by nucleic acid hybridization reactions. Applicant on page 5, paragraph 0029 indicates that these non-covalent protein-binding techniques are known the art. It would have been obvious to use non-covalent attachment techniques to immobilize the enzymes taught by Hendrickson or Forster or Antwerp with the expectation of obtaining similar binding would have been obvious to one of ordinary skill in the art since these techniques are art known binding techniques, especially known to be used to coat medical articles.

Appellant's arguments have been fully considered, but are not found to be persuasive. Appellant agrees that these claims only rely on techniques that were generally known and provides no specific arguments.

3. Claims 1, 11-16, 19-24 and 27are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivan cited in the previous action, in combination with Pinchuk (5,741,331).

Sivan discloses an intravascular apparatus wherein nitric oxide synthase is covalently attached to the carrier. The enzyme either chemically attached to the stent or alternatively entrapped within a polymeric hydrogel that covers the stent. The polymeric material includes polymers and copolymers such as polyethylene, polypropylene, polyacrylic acid and others (col. 3, line 41 through col. 5, line 9 and claims 1 and 4). What is lacking in Sivan is the use of claimed block copolymer comprising polybutylene and acrylates or vinyl aromatics.

Pinchuk while teaching implantable medical devices teaches that polymeric material made from block copolymers of polyolefin and styrene or acrylate is biostable and crack-resistant when implanted in vivo (abstract, col. 1, line 6 through col. 2, line 41, examples and claims).

The use of polymeric material made from block copolymers of polyolefin and styrene or acrylate in the medical device of Sivan would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Pinchuk teaches that these block copolymers are biostable and crack-resistant when implanted in vivo.

Appellant's arguments have been fully considered, but are not found to be persuasive. Appellant while admitting that Sivan discloses a medical device bearing an enzyme, argues that the enzyme in Sivan is either bonded directly to the surface of the article or is entrapped with a hydrogel. These arguments are similar to those put forth by appellants for the rejection of claims over Hendrickson, Antwerp and Pinchuk above, which the examiner has already addressed. .

4. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivan in combination with Pinchuk (5,741,331), further in combination with applicant's statements of prior art.

The teachings of Sivan and Pinchuk have been discussed above. What is lacking in these references is the teaching of immobilizing the enzymes on the medical article through antibody-antigen interactions or by nucleic acid hybridization reactions. Applicant on page 5, paragraph 0029 indicates that these non-covalent protein-binding techniques are known the art. It would have been obvious to use non-covalent attachment techniques to immobilize the enzymes taught by Sivan with the expectation of obtaining similar binding would have been obvious to one of ordinary skill in the art since these techniques are art known binding techniques, especially known to be used to coat medical articles.

Appellant provides no specific arguments with regard to this rejection.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/G S Kishore/

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